

ClariPro GK- γ Hydrophilic PES Membrane Inline Capsule Filters

mdi ClariPro GK- γ gamma sterilizable lab scale hydrophilic PES membrane capsule filters are ready to use, disposable filtration devices. These are specially designed filters incorporating a microglass fiber upstream layer and a downstream PES membrane final layer and are used as pre-filters in biopharmaceuticals process development for difficult to filter solutions.

The microglass fiber layer offers high dirt holding capacity and efficient retention of colloidal particles to give clear downstream in case of difficult to filter turbid solutions. The downstream PES membrane offers absolute retention, and low protein binding along with high flow rates.

The 50 mm devices incorporate a vent to ensure easy removal of entrapped air in the upstream tubing.

Quality Assurance

These filter devices are manufactured in class 10,000 clean rooms under ISO 9001 certified quality management systems and are deeply validated to meet compendia and regulatory requirements.



Applications

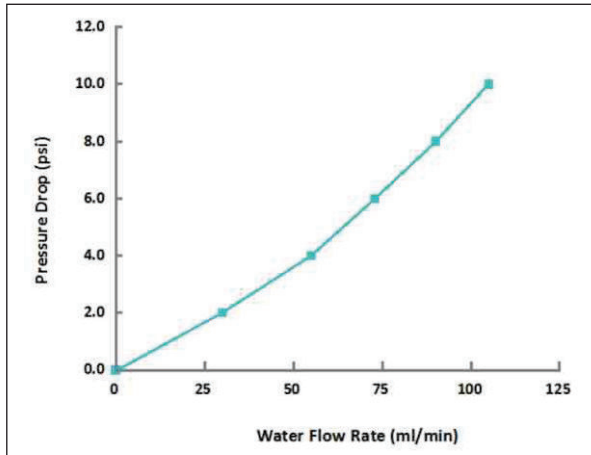
- Precipitate removal post viral inactivation
- Pre-filtration of serum solutions
- Clarification of cell harvest supernatants
- Polishing of turbid solutions

Specifications

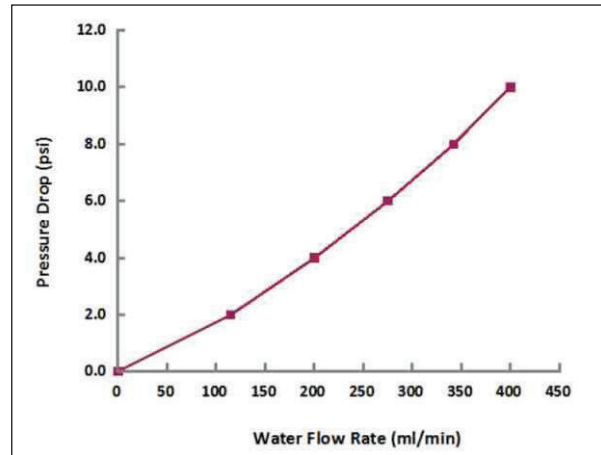
| Construction | | |
|-------------------------------------|---|---|
| Pore Size | 0.1 μ m, 0.2 μ m, 0.5 μ m | |
| Membrane | Hydrophilic PES | |
| Pre-filter | Microglassfiber | |
| Support Layers | Polyester | |
| Body and Core | Polypropylene | |
| Size | | |
| Size | 25 mm | 50 mm |
| Effective Filtration Area (Nominal) | 5 cm ² | 20 cm ² |
| Operational | | |
| Max. Operating Temperature | 60 °C | |
| Max. Differential Pressure | 42 psi (3 Kg/cm ²) @ 30 °C | |
| Sterilization | By Irradiation | Gamma Irradiatable up to 50 kGy |
| | By Autoclave | Autoclavable at 125 °C for 30 minutes, 1 cycle after gamma irradiation. Can not be in-line steam sterilized |
| Assurance | | |
| Toxicity | Passes Biological reactivity Test, <i>In Vivo</i> , as per USP <88> for Class VI plastics | |
| Fiber Release | Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release | |
| Particle Release | The filtrate complies with USP <788> test for particulate matter in injections | |
| Extractables with WFI | Passes test as per USP | |
| Oxidizable Substances | Within limits as specified in USP | |

Water Flow Rates

ClariPro GK- γ 0.5 μ m, 25 mm



ClariPro GK- γ 0.5 μ m, 50 mm



Ordering Information

ClariPro GK- γ 25 mm

| Type | | Size | | Pore Size | | Inlet/Outlet | | Radiation Sterilizable | | X | Sterility | | Pack Size | |
|-----------------------|------|-------|------|-------------|------|------------------|------|------------------------|------|---|---------------|------|-----------|------|
| | Code | Dia | Code | | Code | | Code | | Code | | | Code | | Code |
| ClariPro GK- γ | IGKX | 25 mm | 06 | 0.1 μ m | 36 | Female Luer Lock | M | Yes | R | | Non Sterile | 1 | 100 | 04 |
| | | | | 0.2 μ m | 01 | Male Luer Slip | N | No* | X | | Gamma Sterile | 3 | | |
| | | | | 0.5 μ m | 04 | 1/8" Hose Barb | H | | | | | | | |
| | | | | | | 1/4" Hose Barb | B | | | | | | | |

Example

| | | | | | | | |
|------|----|----|----|---|---|---|----|
| IGKX | 06 | 04 | MN | R | X | 1 | 04 |
|------|----|----|----|---|---|---|----|

* Gamma irradiated filters cannot be gamma sterilized again

Example for Non Sterile: IGKX0604MNRX104

Example for gamma Sterile: IGKX0604MNXX304

ClariPro GK- γ 50 mm

| Type | | Size | | Pore Size | | Inlet/Outlet | | Radiation Sterilizable | | X | Sterility | | Pack Size | |
|---------------------------------|------|-------|------|-------------|------|------------------------|------|------------------------|------|---|---------------|------|-----------|------|
| | Code | Dia | Code | | Code | | Code | | Code | | | Code | | Code |
| ClariPro GK- γ | IGKX | 50 mm | 10 | 0.1 μ m | 36 | 1/4" SHB | B | Yes | R | | Non Sterile | 1 | 10 | 02 |
| ClariPro GK- γ with vent | VGKX | | | 0.2 μ m | 01 | **3/4" Sanitary Flange | S | No* | X | | Gamma Sterile | 3 | | |
| | | | | 0.5 μ m | 04 | | | | | | | | | |

Example

| | | | | | | | |
|------|----|----|----|---|---|---|----|
| IGKX | 10 | 04 | SS | R | X | 1 | 02 |
|------|----|----|----|---|---|---|----|

* Gamma irradiated filters cannot be gamma sterilized again

Example for Non Sterile: VGKX1004BBRX108

Example for gamma Sterile: VGKX1004BBXX308

** 3/4" Sanitary Flange are available as Outlet Only for ClariPro GK- γ with vent.

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